

AMENDMENTS TO THE SPECIFICATION

Please amend the paragraph beginning on page 1, line 6 as follows:

(Currently Amended) The present application is a continuation of U.S. Application Serial No. 09/956,418 filed September 18, 2001, pending, which is a continuation of U.S. Application Serial No. 09/087,511 filed May 29, 1998 which is now U.S. Patent 6,338,712, issued January 15, 2002, which is a continuation-in-part application of ~~co-pending patent~~ application Serial Number 08/936,184 filed on September 17, 1997, which is now U.S. Patent No. 6,019,72, issued February 1, 2000 by the inventors of the present application. The disclosure of the just referenced patent application is incorporated herein by reference. U.S. Application Serial Numbers 09/956,418; 09/087,511 and 08/936,184 and U.S. Patent Nos. 6,338,712 and 6,019,722 are hereby incorporated by reference thereto, in their entireties.

Please amend the paragraph beginning on page 10, line 13 as follows:

(Currently Amended) While the art has included several inventions intended to support the heart during coronary bypass surgery of the circumflex coronary artery, these inventions have several drawbacks that have hindered their acceptance in the art. For example, the use of nets to support the heart exposes the heart to fine ~~stands~~ strands which impinge on the heart and may cause damage. Furthermore, nets may impede the surgical target and require special techniques or procedures to remove the net from the surgical target area. This is especially onerous if the net mesh is fined. Flat cloth tapes are a form of net, and may damage the heart due to a rough texture of the cloth and the small area of contact between the tape strands and the heart. Further, tapes and similar devices that do not have large surface areas contacting the heart may not support the heart in a uniform

Please amend the paragraph beginning on page 11, line 2 as follows:

(Currently Amended) Therefore, there is a need for a manipulation system for use in cardiac surgery which will support the heart in position for coronary bypass surgery of the circumflex coronary artery in a manner that ~~tool~~ will not damage the heart yet will provide easy access to the surgical target and keeps working while cardiac output is maintained.

Please amend the paragraph beginning on page 19, line 15 as follows:

(Currently Amended) A form of the system of the present invention can be used in minimally invasive surgery. The system may include a handle on the gross ~~support~~ support means to move the gross support means as required, and a handle can be placed on the target-immobilizing means to move that means as necessary as well. The distal ends of ~~a handles~~ the handle are located to provide access to ~~the handle~~ the handle while remaining unobtrusive during surgery. Detachable handles could also be used whereby the handles are ~~revoved~~ removed after correct placement of the head.

Please amend the paragraph beginning on page 21, line 5 as follows:

(Currently Amended) Figure 8 is a perspective view of a ~~beating~~ system for manipulating a beating heart during cardiac surgery embodying the present invention.

Please amend the paragraph beginning on page 27, line 1 as follows:

(Currently Amended) element 52. Vacuum ports ~~62~~ 62c and 62p are defined through the cup-shaped element at apex 58 to be fluidically connected with a vacuum source for securing the heart in place in the cup-shaped element. A vacuum source V is fluidically connected to holes ~~62~~ 62c and 62p via main support arm 64 which has one end thereof fixed to a stationary support S (see Figure 5), such as the operating table, or a rib spreader, and the other end thereof attached to the cup-shaped element via fastener 66 attached to anchor 68. A manifold-like portion 70 of the cup-shaped element distributes the vacuum to the various ports, such as ports ~~62~~ 62c and 62p to be applied to secure retractor 50 to the heart. An alternative form of the retractor includes a separate hose 72 to transfer vacuum to the manifold 70. Ribs 60 keep heart fat from clogging the vacuum manifold section.

Please amend the paragraph beginning on page 29, line 20 as follows:

(Currently Amended) As was discussed in the parent disclosure, during operation of the heart, the left ventricle is a conical shaped cavity which is narrowest at the apex. It shortens both in length ~~an~~ and in diameter during a pumping stroke (contraction). Since the volume of blood displaced is more

dependent on the reduction in diameter (square) than the shortening in length (first power), any measure which reduces the shortening of the diameter of shortening is very detrimental. Also, the

Please amend the paragraph beginning on page 31, line 1 as follows:

(Currently Amended) myocardium to move during heart operation without unduly affecting the attachment of the element to the heart. Specifically, the suction cup of the present invention applies suction to the heart surface from a source of suction (not shown, but discussed in the parent disclosure). Suction cup 200 of the present invention is best shown in Figure 7A which shows a suction cup that is most useful with non-flaccid tissue in which it is easier to make the suction cup conform to the tissue than to force the tissue to conform to the suction cup, and Figure 7B which shows a suction cup that is most useful with flaccid tissue which is easier to force to ~~conform~~ conform to the shape of the suction cup. Both suction cups 200 can be compared to a prior art suction cup S shown in Figures 6A and 6B. As shown in Figures 6A and 6B, prior art suction cup S includes a single chamber C that is fluidically connected to a suction line L and which has a rim R for engaging the surface, such as tissue T, to which suction cup S is attached. Suction pressure is applied over an area A which corresponds to the area of the suction line L. As will be understood by those skilled in the art, if tissue T moves it can move away from rim R thereby breaking the suction being applied to tissue T. Still further, if tissue T moves, it might move into suction line L thereby interfering with application of suction to the tissue, as is indicated in Figure 6B. This latter situation is likely since the maximum suction force is applied over area A and will tend to distort tissue T in the manner indicated in Figure 6B. Such distortion also tends to move the tissue away

Please amend the paragraph beginning on page 32, line 2 as follows:

(Currently Amended) However, suction cup 200 shown in Figures 7A and 7B does not have these drawbacks because it includes a plurality of chambers and a means for preventing tissue from interfering with suction being applied thereto. Specifically, suction cup 200 is a multi-section suction cup which includes a first chamber 202 having a flexible rim 204 for engaging the tissue M of a heart, and a second chamber 206 for fluidically connecting first chamber 202 to the source of suction via suction line 208. Second chamber 206 of the suction cup has a size that is different from the size of first chamber 202, and a shoulder 209 is formed at the connection between first and second chambers 202

and 206. A mesh grid element 210 is connected to the suction cup, preferably adjacent to shoulder 209, and spans ~~first~~ second chamber 206. ~~flexible~~ Flexible rim 204 is flexible in a plurality of planes to accommodate multiplanar movement of the surface of the beating heart without breaking contact between the surface of the heart and flexible rim 204.

Please amend the paragraph beginning on page 32, line 18 as follows:

(Currently Amended) As can be understood from Figures 7A and 7B, suction cup 200 will not break suction with tissue T even if the tissue is drawn into the suction cup and a large area of applied suction is maintained due to the large area A' of second ~~of first~~ chamber 206 vis á vis area A of suction cup S. Thus, suction cup 200 is able to adapt to movement of the heart and movement of the myocardium while maintaining a large suction force on the tissue. This permits smaller amounts of myocardium to be affected by the system of the present invention than even the parent retractor. Since chamber

Please amend the paragraph beginning on page 35, line 2 as follows:

(Currently Amended) Frame 302 includes ~~including~~ a cross bar 303 that has a multiplicity of teeth 303T thereon for a purpose that will be understood from the following disclosure. Frame ~~300~~ 302 further includes means for engaging the patient to support the frame in position in the patient. A preferred form of this means includes two sternal spacers 304 which set the depth of the frame ~~into~~ into the chest cavity and keep the frame from twisting as the lungs inflate and which are connected to cross bar 303 by a ratchet-like mechanism 305 that has teeth which engage teeth 303T when the spacers are in the desired location. The frame is expanded inside the pericardial cavity with the cross bar. A handle 305H is operated to set the teeth of the mechanism 305 to teeth 303T. The frame can be either C-shaped or hoop shaped and can be secured to the patient or to an outside stable support. Other anchor means can be used as well as will occur to those skilled in the art based on the teaching of the present disclosure, and these means are intended to be within the scope of this disclosure as well.

Please amend the paragraph beginning on page 35, line 19 as follows:

(Currently Amended) As was the case in the parent disclosure, a source of suction is located

outside the patient and is used to attach various elements to the patient's heart. Most often, a source of ~~vacuum~~ vacuum is from the operating room source which provides approximately 100 to 180 mm of Hg vacuum. The source of suction is not shown herein as those skilled in the art will understand where such source is best located and what source is best suited to the particular application based on the teaching of the

Please amend the paragraph beginning on page 36, line 2 as follows:

(Currently Amended) As shown in Figure 8, system 300 includes a suspension head mechanism 312 movably mounted on frame ~~300~~ 302 for lifting the heart. Mechanism 312 includes a head 314 which engages the heart and which is shown in Figure 9 as being located near the apical region of the right ventricle to prevent collapse of the right ventricle during manipulation of the heart, ~~as~~ As is also shown in Figure 9, suspension head 314 at least partially overlies the right ventricle. Suspension head mechanism 312 includes a flexible means 316, such as a spring, for connecting flexible head 314 to arm 318 and for permitting multiplanar relative movement between the beating heart and arm means 318 mounting suspension head 314 on frame means ~~300~~ 302. Suspension head 314 includes a suction cup such as disclosed above in Figures 7A and 7B connected to the source of suction and which includes a flexible rim engaging the myocardium of the heart and being flexible in a plurality of planes so multiplanar movement of the myocardium during operation of the heart will be accommodated by the flexible rim whereby suction applied to the myocardium by the suction cup will not be broken by separation of the myocardium from the suction cup. As discussed above, the suction cup of head 314 includes means, such as the above-discussed mesh grid, for preventing heart tissue from interfering with suction being applied to the myocardium via head 314.

Please amend the paragraph beginning on page 37, line 1 as follows:

(Currently Amended) and anchor element 324. Anchor element 324 includes a base ~~326~~ 324A which is movably mounted on cross bar ~~302~~ 303 and has internal teeth that engage teeth 303T, and a lever system for locking the internal teeth of element 324 to teeth 303T when desired. A further lever-operated mechanism locks corresponding elements in arm 318 whereby arm 318 is rendered rigid. Arm 318 includes a flexible central line extending from head 314, through flexible element 316 to anchor element 324 and a plurality of relatively movable sections, such as balls 326 interposed between links

328, on the central line. A lever 330 is connected to the central line and when the lever is operated, the elements 326 and 328 are forced together to render the arm rigid. In this manner, the suspension head 314 can be easily maneuvered on a flexible arm into the desired position and then locked into that position by rendering arm 318 rigid. Flexible means 316 permits multiplanar movement of suspension head 314 even after arm 318 is made rigid whereby movement of a beating heart is accommodated by suspension head mechanism 312. When suction is applied to the heart via head 314 the heart will be suspended and can be lifted into the desired position and orientation for cardiac surgery without interrupting cardiac output. The combination of the suction cup, the flexible/rigid arm, the flexible means and the location of the head on the heart effect this result. Various forms of head 314 can be used without departing from the scope of the present invention, and a second form of the head is shown in Figure 17 as head 314' and which includes a multiplicity of chambers. Any of

Please amend the paragraph beginning on page 40, line 1 as follows:

(Currently Amended) support means 400 includes a head 402 that is engaged with the heart and which is movably connected to frame ~~300~~ 302 by an arm mechanism 403 similar to arm 318 to be flexible and movable with respect to the heart and with respect to frame ~~300~~ 302 when desired, and then rendered rigid by operation of a lever 404 of an anchor mechanism 406 that can be located on cross bar ~~302~~ 303 or on one of the sternum retractors 304. Operation of the flexible arm 403 is identical to that of arm 318 and thus will not be again discussed.

Please amend the paragraph beginning on page 40, line 16 as follows:

(Currently Amended) Head 402 is shown in Figures 12-14C as including a rigid support section 406 connected to a flexible section ~~408~~ 488 having malleable rod means 410 received in bores 411 defined in head 402 for retaining a configuration that has been set for head 402 and for connecting head 402 to the arm 403 for mounting gross support means 400 on frame 302. Head 402 can include a plurality of sections which are movable relative to each other and means for maintaining those section in a selected relative orientation. In this manner, head 402 can be shaped to best support the heart and can be adjusted to meet the needs of an individual heart. As head 314 is also adaptable to the size and shape of an individual

Please amend the paragraph beginning on page 41, line 5 as follows:

(Currently Amended) As shown in Figures 14A-14C, head 402 includes means for applying suction from the source of suction to the heart. AS best shown in Figure 14A, this means includes a mesh grid means 210 attached to head 402 and spanning a first chamber 420 above a suction applying manifold 422 that is fluidically connected to the source of suction by a suction line 208 for preventing heart tissue from interfering with suction applied by suspension head 402 to the heart. A frame 424 maintains mesh grid means 210 in place on head 402, and ribs, such as rib 426 and rib 428 can be used to maintain the desired position of mesh grid element 210 with respect to suction holes 208 at the end of the suction line.

Please amend the paragraph beginning on page 42, line 8 as follows:

(Currently Amended) Alternative forms of the frame ~~300~~ 302 can be used without departing from the scope of the present disclosure, just so the frame is located to move with the patient. Thus, a frame ~~300'~~ 302' shown in Figure 26 can be used. Frame 302' essentially completely surrounds the heart and includes elements 304' for engaging the patient to support frame 302' in place ~~as a~~ . A handle 302H can be used to adjust the location of frame 302'. Handle 302H includes a knob 302K which operates a pinion system for engaging teeth 303T to adjust the size of the frame circumference as indicated by arrow 302S in Figure 26.